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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PALABRICA, RICARDO J

ART UNIT

PAPER NUMBER

3663

DATE MAILED: 02/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/932,531	Applicant(s) AKERS, DOUGLAS W.	
	Examiner Rick Palabrica	Art Unit 3663	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 20-24, 26-28 and 30-40 is/are pending in the application.
- 4a) Of the above claim(s) 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-24, 26-28 and 30-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's 12/20/05 Amendment, which canceled claims 1-3, 5, 7, and 8, submitted a replacement drawing, amended the specification and traversed the rejection of claims is acknowledged. The replacement drawing is accepted.

Claims 20-24, 26-28 and 30-40 are pending and examined in this Office action. Claim 4 has been withdrawn from consideration. Applicant has specifically canceled claim 8 but incorrectly labeled claim 8 as "previously presented" in said Amendment. This error must be corrected by canceling claim 8.

2. Applicant's arguments that traversed the rejection of claims 20-24, 26-28 and 30-40 under 35 U.S.C. 112, first and second paragraphs, have been fully considered but found not convincing.

The examiner has raised several issues regarding the sufficiency of applicant's disclosure, and has provided documentary evidence to support his reasoning. Applicant's main argument is that it would not require undue experimentation to arrive an operative embodiment of the applicant's invention. The examiner does not agree. Note that the examiner's conclusions are based on all of the evidence of this case, including the specifications and the drawings, as well as case law and the MPEP.

Applicant's claims require the use of algorithms (e.g., Doppler broadening, positron lifetime, etc.), detector(s), a photon source, and a data processor. Thus, to enable an artisan to make and use an operative embodiment, one must first know which

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particular algorithm(s) to use, and how and in what manner the data from the detector(s) are to be analyzed in the "data processor."

It is the examiner's position that applicant's specification basically sets forth the algorithms and data processor as "black boxes" without sufficient details of internals thereof, to enable an artisan to make and use an operative embodiment of the invention, without undue experimentation. See MPEP 2164.06 and *In re Ghiron*, 169 USPQ 723.

Note that an algorithm is a general mathematical approximation of a physical phenomenon. Different algorithms can be used to approximate the same physical event or phenomenon and, depending on the particular situation, circumstances, etc., one of these known algorithms will give a more accurate result than the others.

As an example, the specification indicates that there are different known Doppler broadening algorithms but, fails to disclose which of these known algorithms would be suitable for use in the present invention. Accordingly, due to this failure, one must resort to a trial-and-error process to determine which of the known algorithms to use and, such is considered undue experimentation.

This is especially so since all algorithms contain "constants" that are used to apply the algorithm to a "specific situation." These "constants" are based on various boundary conditions, etc., of the "specific situation" or, in mathematical terms, each of these "constants" are defined as a function of these boundary conditions, wherein different boundary conditions are given different weights and combined in a given manner (e.g., multiplied by a number (e.g., 3), squared, and then added together, etc.).

Thus, before one can even apply a given algorithm to a “specific situation”, one must first determine the mathematical equations used to determine each of the “constants” in the given algorithm.

It is the examiner’s position that neither the applicant’s specification nor the art of record, provides an enabling disclosure of the particular mathematical equations to be used for determining each of the different “constants” in each of the different algorithms.

It is the examiner’s position that it would be undue experimentation for an artisan to utilize a trial-and-error process to go through all of the possible mathematical equations (with all of the possible weighted boundary conditions, etc.) for each of the various known different Doppler broadening algorithms and for each of the various known different positron lifetime algorithms, etc., to finally determine which one to use in applicant’s invention. The examiner’s conclusions are supported by MPEP 2164.06(a) and the case law cited therein. Applicant’s illustration of block diagrams labeled data processing system, Doppler broadening, positron lifetime, etc., with no description of internals thereof, is similar to the situation in *In re Ghiron* 169 USPQ 723. Applicant’s case is also considered analogous to *In re Scarbrough* 182 USPQ 298, wherein Scarbrough had a claim directed to a system of several component parts referred to by a generic name and overall ultimate function. The court concluded that there was no enabling disclosure because the specification did not describe how “complex elements known to perform broadly recited functions in different systems would be adaptable for use in Appellant’s particular system with only reasonable amount of experimentation.”

While the above, by itself, is considered evidence of undue experimentation, one is still not done!

Applicant's specification on pages 18, 28 refer to some of the characteristics of the specimen that is desired for each algorithm to assess. Applicant's data processor utilizes the algorithms to process the data from the detector and then, in some undisclosed manner, to further process the output of the algorithm to provide an indication of the presence or absence of a lattice defect or a "changing" condition. This indication is actually a probability of a lattice defect being present, since this is a non-destructive analysis.

If one sets the conditions too loosely, too many specimens will be inaccurately indicated as having a lattice defect. On the other hand, if one sets the conditions too tightly, the inventive system will inaccurately indicate too many specimens as not having a lattice defect when they actually do. In the art of activation analysis, where the claimed invention belongs, the boundary conditions have a profound effect on the accuracy of the results. The situation for applicant's claimed invention is similar, for example, to Schultz et al. (U.S. 5, 200,626) who disclose a method and an apparatus for detecting hidden explosives by pulsed neutron and x-ray interrogation. They teach that if the threshold level of the system is adjusted so as to detect small quantities of nitrogen, then a high false-positive rate results due to the presence of innocent nitrogen containing materials, leading to the necessity of searching an excessive number of packages by hand. On the other hand, if the threshold level is set high to avoid false positives, then the likelihood that actual explosives will escape detection is increase.

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In addition, applicant's invention is not just the determination of the presence or absence of just a single lattice defect, which, in itself, would not provide any useful information, but rather, whether there are present enough lattice defects to cause metal fatigue, etc. (as indicated in applicant's specification).

Clearly, it is undue experimentation to determine a suitable data processor for determining how and in what manner, the outputs from each of the algorithms is to be processed so as to provide a reasonably accurate non-destructive determination as to whether or not the specimen in question has sufficient lattice defects to be of concern (as indicated in applicant's specification). Note that this is in addition to determining which of the several known Doppler broadening algorithm and which of the several positron lifetime algorithms should be used after going through a trial-and-error process involving different mathematical equations with different weighted boundary conditions, as already set forth above.

However, one is still not done!

The only way to determine whether or not the "chosen" specific Doppler broadening algorithm, the "chosen" specific positron lifetime algorithm, etc., the "chosen" manner of further manipulating or analyzing the output of the algorithm, actually provides a reasonable determination of the presence of enough lattice defects to be of concern, is by doing a further analysis of the specimen (such as a destructive testing/analysis) to determine the actual quantity of said lattice defects present and noting how closely the result of this actual testing/analysis correlates to the result from applicant's non-destructive analysis.

Further, to obtain reasonable statistical analysis, one would have to do this for a plurality of specimens. Clearly, such would present undue experimentation.

Additionally, applicant has some claims that require the presence of both a Doppler broadening algorithm and a positron lifetime algorithm, and which require the data processor in some undisclosed manner to combine the outputs of these algorithms to indicate a lattice defect.

First, the appropriate algorithm has to be selected from a plurality of available algorithms that applicant himself admits and as taught by the references cited by the examiner in the previous Office action. This selection has to be performed for each of the Doppler broadening algorithms, each of the positron lifetime algorithms, each of the 3D imaging algorithms, and each of the selective activation algorithms.

Next, the results of applying the algorithms have to be combined in order to produce an output data indicative of the presence or absence of a lattice defect (e.g., see claim 37). Since applicant has refused to disclose how these algorithms have to be combined, an artisan will have to determine by trial-and-error that may include hundreds or thousands of possible combinations, starting, for example, with 5% Doppler and 95% positron lifetime and up to 95% Doppler with 5% positron lifetime. Additionally, for each selected combination, the plurality of constants inherently associated with each selected algorithm has to be evaluated.

Then, the results of these hundreds or thousands of possible combinations must be compared to the results from the above referred to as “destructive testing/analysis” of each specimen to determine the manner of combining.

Additionally, applicant's specification on pages 17, 29 states that both the positron lifetime algorithm and the 3-D algorithm, generally each requires at least two detectors. However, claims such as claims 21, 33, 34, 36, 37 require the use of a positron lifetime algorithm with only a single detector and claims 24, 32, 35, 36, 38 require the use of a 3-D algorithm with only a single detector!

Applicant's disclosure is thus clearly insufficient and non-enabling as to which specific known positron lifetime algorithm can be used with only a single detector and, which specific 3-D algorithm can be used with only a single detector. This is especially so in view of applicant's own statements in his specification that these algorithms generally require at least two detectors.

Claims such as claims 21, 22, 27, 28, 33, 34, 36, 37 refer to "changing" characteristic of the system. The specification on page 28 indicates that the positron lifetime algorithm can be used to determine the "mean lifetime" of the positron (but fails to disclose how) and, that the mean lifetime is used to derive information relating to the changing characteristics of the system (but again fails to disclose how). The specification is thus insufficient and non-enabling as to how and in what manner said mean lifetime and changing characteristic determinations can be accomplished. Applicant's reference in the drawings to a box labeled data processor and the reference to such in the specification is thus even more place them in the category of a "black box" (see MPEP 2164.06 and *In re Ghiron* 169 USPQ 723).

Applicant shows in Fig. 6 that there is feedback between the data processing system and each one of the elements, Doppler broadening (62), positron lifetime (64),

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3-D imaging (66) and selective activation (68). This feedback is indicated in Fig. 6 as double headed arrows between the data processing system and each of elements 62, 64, 66. There are no details in the specification of how the parts should be interconnected, timed and controlled so as to obtain the specific operations desired by the applicant (see, for example, *In re Gunn* 190 USPQ 402, 406). Additionally, there is no discussion as to what factors comprise the feedback for each one of the four specific elements, when such feed back occurs, whether or not feedback to one algorithm also comes from the other algorithms, etc. This feedback arrangement provides further proof of necessary modification, consistent with the issue previously raised by the examiner. If no modification of results is required, applicant would not have indicated this feedback mechanism in his disclosure.

Applicant states in the specification that the selective activation algorithm allows the user to activate certain isotopes or positron emitters (e.g., see page 30, paragraph 0060). Applicant then shows in Fig. 2 that depending on the isotopes or positron emitters selected by the selective activation algorithm, one uses either a rapid activation/analysis (where the half lives of the selected isotopes are short) or a normal activation/analysis (where the half lives are long). Applicant shows examples of long half-life positron emitters in Table I and short half-life positron emitters in Table II. Metal alloys can have both long half-life positron emitters and short half-life positron emitters, even only as impurities. Thus, the specification is insufficient and non-enabling as to how and in what manner: a) the selective activation algorithm would select the isotope

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to be activated; and b) the type of activation/analysis to be used, where a specimen contains both long half life positron emitters and short half life positron emitters.

Applicant argues that his disclosure is enabling because “the level of disclosure in the pending application is on par with the level of disclosure provided by issued U.S. patents” (underlining provided).

The examiner disagrees. First, applicant’s allegation is misleading and inaccurate. He purports to prove his case by comparison with a plurality of issued patent in the same field as his application, by his statement:

“As will be described in greater detail below, those patents provide a similar level of disclosure to that of the pending application” (see page 16, lines 15+).

However, the only patent applicant later refers as basis for his argument is a SINGLE patent, i.e., U.S. Patent 6,178,218. A single patent, let alone a patent by the applicant, neither provides a sufficient data base nor allows an unbiased basis for drawing conclusions on the issue.

Second, the issuance of the cited patent is not dispositive of the issues raised by the current examiner because his issues are different from those raised by another examiner who examined the application for the cited patent.

Applicant also argues that his written description is enabling because: i) said algorithm “is described in paragraphs 0028, 0055, and 0056 of the written description” (underlining provided); and ii) the written description states that “in one embodiment, the Doppler broadening algorithm may be that disclosed in the U.S. Patent No. 6,178,218, to Akers, which is specifically incorporated by reference into the written description.” These arguments are not convincing.

As to argument i), the paragraphs cited by the applicant makes mention of the use of the algorithms but does not describe the algorithms themselves. Mentioning the use is different from "describing the algorithm."

As to argument ii), there are two embodiments of the claimed invention, i.e., the first embodiment is shown in Fig. 1 and the second embodiment is as shown in Fig. 6. Applicant's statement is vague and indefinite as to which of the two embodiments he is referring to by the phrase, "one embodiment". Also, the invention in U.S. Patent No. 6,178,218, is directed to an embodiment that uses ONLY one detector (see Fig. 1 in said a patent). In contrast, claims such as claims 22 and 28 of the instant application, are directed to TWO detectors (see Fig. 6 in the instant application). Obviously, the algorithm for the one-detector system of U.S. Patent No. 6,178,218, cannot be directly used for the two-detector system of the instant application, at least because of differences in the number of spectra detected. At a minimum, some modifications have to be made, e.g., combining the results according to some weighting scheme. The specification does not describe how and in what manner such modification should be done. Again this is the issue of modification of algorithm that the examiner has previously raised, but which the applicant fails to continue to address.

In summary, the examiner has demonstrated above that applicant's disclosure is insufficient and non-enabling, and that undue experimentation would be required by an artisan to make and use an operative embodiment of applicant's claimed invention. The

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examiner's position is supported by the following sections of the MPEP and the case laws cited therein.

2164.06(a) Examples of Enablement Issues-Missing Information

"It is common that doubt arises about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation.

I. ELECTRICAL AND MECHANICAL DEVICES OR PROCESSES

For example, a disclosure of an electrical circuit apparatus, depicted in the drawings by block diagrams with functional labels, was held to be nonenabling in *In re Gunn*, 537 F.2d 1123, 1129, 190 USPQ 402, 406 (CCPA 1976). There was no indication in the specification as to whether the parts represented by boxes were "off the shelf" or must be specifically constructed or modified for applicant's system. Also there were no details in the specification of how the parts should be interconnected, timed and controlled so as to obtain the specific operations desired by the applicant.

In re Ghiron, 442 F.2d 985, 169 USPQ 723 (CCPA 1971), involved a method of facilitating transfers from one subset of program instructions to another which required modification of prior art "overlap mode" computers. The Board rejected the claims on the basis, *inter alia*, that the disclosure was insufficient to satisfy the requirements of 35 U.S.C. 112, first paragraph and was affirmed. The Board focused on the fact that the drawings were "block diagrams, i.e., a group of rectangles representing the elements of the system, functionally labeled and interconnected by lines." 442 F.2d at 991, 169 USPQ at 727. The specification did not particularly identify each of the elements represented by the blocks or the relationship therebetween, nor did it specify particular apparatus intended to carry out each function.

An adequate disclosure of a device may require details of how complex components are constructed and perform the desired function. The claim before the court in *In re Scarbrough*, 500 F.2d 560, 182 USPQ 298 (CCPA 1974) was directed to a system which comprised several component parts (e.g., computer, timing and control mechanism, A/D converter, etc.) only by generic name and overall ultimate function. The court concluded that there was not an enabling disclosure because the specification did not describe how "complex elements known to perform broadly recited functions in different systems would be adaptable for use in Appellant's particular system with only a reasonable amount of experimentation" and that "an unreasonable amount of work would be required to arrive at the detailed relationships appellant says that he has solved." 500 F.2d at 566, 182 USPQ at 302.

2164.06 Quantity of Experimentation - 2100 Patentability

II. EXAMPLE OF UNREASONABLE EXPERIMENTATION

In *In re Ghiron*, 442 F.2d 985, 991-92, 169 USPQ 723, 727-28 (CCPA 1971), functional "block diagrams" were insufficient to enable a person skilled in the art to practice the claimed invention with only a reasonable degree of experimentation because the claimed

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invention required a "modification to prior art overlap computers," and because "many of the components which appellants illustrate as rectangles in their drawing necessarily are themselves complex assemblages . . . "

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20-24, 26-28 and 30-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The reasons are the same as those stated in section 4 of the 9/14/05 Office action, as further clarified in section 2 above, which reasons are herein incorporated.

4. Claims 20-24, 26-28 and 30-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The reasons are the same as those stated in section 5 of the 9/14/05 Office action, as further clarified in section 2 above, which reasons are herein incorporated.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rick Palabrica whose telephone number is 571-272-6880. The examiner can normally be reached on 6:30-5:00, Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jack Keith can be reached on 571-272-6878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RJP
February 6, 2006

A handwritten signature in black ink, appearing to read "R. Palebrica", with a long horizontal stroke extending to the right.